OCT 1 9 2001

# 510(k) SUMMARY

**A. Submitter Information:**

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| Submitter: | MEDCOMP®<br>1499 Delp Drive<br>Harleysville, PA 19438<br>(215) 256-4201 Telephone<br>(215) 256-1787 Fax |
| Contact: | Jeanne M. Cush |
| Date Prepared: | July 25, 2001 |

**B. Trade Name:** Medcomp Ash Split-Cath
Common Name: Hemodialysis Catheter, Implanted
Classification: 78 MSD
C.F.R. Section: 876.5540

**C. Predicate Device:** K972207 Medcomp Ash Split-Cath

**D. Device Description:**

The Medcomp Ash Split-Cath is a polyurethane, double lumen catheter used to remove and return blood through two-segregated lumen passages. Both lumens are "D" shaped, tapered at the distal tip, with six side holes. The distal venous lumen extends beyond the arterial lumen to reduce recirculation. The fixed polyester cuff allows for tissue ingrowth for long term placement.

The lumens are connected to the extensions via a soft pliable hub with suture wing. Red and blue luer connectors and clamps identify the arterial and venous extensions. The clamps incorporate I.D. Rings which indicate priming volume and site care information.

**E. Intended Use:**

The Medcomp Ash Split-Cath is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein of an adult patient. Alternate insertion site is the subclavian vein as required.

**F. Comparison to Predicate Device:**

The technological characteristics of the Ash Split-Cath are substantially equivalent to the predicate in terms of intended use, insertion method, anatomical location, materials, design, performance, labeling, manufacturing process and method of sterilization.

The Ash Split-Cath modifications include:

- Addition of a strain relief to hub to cuff location
- Pre-split lumens
- Additional lengths of 24cm, 36cm and 40cm

The principles operation and basic design remain unchanged.

**G. Performance Data:**

In Vitro performance data for the modified Ash Split-Cath includes:

- Lumen to hub tensile strength
- Alcohol affects testing
- Air leakage
- Liquid leakage

Clinical data was not deemed necessary since in-vitro testing was sufficient To demonstrate safety and effectiveness by way of comparison to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2001

Ms. Jeanne M. Cush
Senior Regulatory Affairs Associate
Medcomp®, Inc.
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K013162
Trade/Device Name: 14F x 24cm Ash Split-Cath, Model ASPC24
14F x 28cm Ash Split-Cath, Model ASPC28
14F x 32cm Ash Split-Cath, Model ASPC32
14F x 36cm Ash Split-Cath, Model ASPC36
14F x 40cm Ash Split-Cath, Model ASPC40
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: September 20, 2001
Received: September 21, 2001

Dear Ms. Cush:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# INDICATIONS FOR USE

510(k) Number: K013162

Device Name: Medcomp Ash Split-Cath

Indications for use:

The Medcomp Ash Split-Cath is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein of an adult patient. Alternate insertion site includes the subclavian vein as required.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013162